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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,380	08/30/2001	S. Grant Mulholland	10303-2 US	7757

7590 09/27/2002  
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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

2c

<b>Office Action Summary</b>	Application N . 09/943,380	Applicant(s) MULHOLLAND ET AL.	
	Examiner Ann Y. Lam	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 65-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-11, 13-25, 30-34, 39-42, 44-52 and 57-64 is/are rejected.
- 7) ☒ Claim(s) 3-6, 12, 26-29, 35-38, 43 and 53-56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 13, 16, 17, 30, 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In these claims, Applicant claims a particular element to have a dimension that is relative to a patient's body part. The dimensions are indefinite because a patient's body part varies depending on which patient is used.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 9-11, 14-21, 23, 30, 32, 33, 34, 39, 41, 42, 45-48, 50, 58-61 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Giglio, 5,085,650.

As to claims 1, 33, 61 and 64, Giglio discloses a base member (26) that is capable of being non-meltable, and is sized to prevent insertion of said base member into said urethra; a reinforcement (16 and 22) that is capable of being non-meltable and

has a length having a first end and a second end, said first end attached to said base member and projecting from said base member; and a meltable portion (22) formed around a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end, see Figure 3, said meltable portion sized for insertion into said urethra, see column 3, lines 19-22.

As to claims 2, 34, the base member (26) is shaped for handling.

As to claims 7, 39, the base member (26) is sized to fit within the labia minora.

As to claims 9, 10, 41, the reinforcement first end (16) is considered embedded within the base member, and projects perpendicular from said base member.

As to claims 11, 42, the reinforcement (16) comprises a rod.

As to claim 14, the reinforcement is sized such that upon insertion into the urethra, the second end of the reinforcement is entirely within the meltable portion. (The reinforcement is considered to be a portion of (16 and 22) that does not have medicament that melts, see column 3, lines 12-13.)

103 As to claim 15, the second end of the reinforcement extends outside the meltable portion. (The reinforcement is considered to be a portion of (16 and 22) that does not have medicament that melts, see column 3, lines 12-13.)

As to claims 16, 17, 59, 60, the reinforcement is considered to have the claimed dimensions.

As to claims 18-21, 45-48, a restraint as claimed is disclosed at (22).

As to claims 23, 50, the meltable portion comprises the therapeutic agents as claimed, see column 3, lines 14-18.

As to claim 30, the meltable portion is sized to fit entirely within the urethra, see column 2, lines 66-67.

As to claim 32, 58, the meltable portion is capable of melting within about 2 minutes to about 60 minutes, see column 3, lines 12-18.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 25, 31, 51, 52, 57, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giglio, 5,085,650.

Giglio discloses the invention substantially as claimed.

As to claims 24, 25, 31, 51, 52 and 57, it would have been obvious to form the meltable portion having the dimensions as claimed, as would be necessary to fit inside a urethra, as taught by Giglio, see column 2, lines 66-67.

As to claims 62 and 63, it would have been obvious to wait for about 1 minute to about 10 hours to deliver the therapeutic agent, as may be necessary to deliver the agent.

Claims 8, 13, 22, 40, 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giglio, 5,085,650, in view of Place et al. 5,919,474.

Giglio discloses the invention substantially as claimed, except for the base member being formed from the materials as claimed, and the meltable portion and reinforcement comprising the materials as claimed.

Place et al. discloses a urethral suppository comprised of plastic, see column 9, line 31. It would have been obvious to form the Giglio suppository from plastic as taught by Place et al.

Place et al. also discloses that the agent may be a biodegradable polymer, see column 8, lines 50-52. It would have been obvious to provide a biodegradable polymer as the agent in the Giglio suppository device as taught by Place et al..

#### ***Allowable Subject Matter***

Claims 3-6, 12, 26-29, 35-38, 43, 53-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's argument with respect to the restriction requirement is moot since Examiner examined claims 61-64 also.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.  
September 22, 2002

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER  
9/22/02